

60th Medical Group (AMC), Travis AFB, CA
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20170012A

DATE: 6 November 2017

PROTOCOL TITLE: Assessment Of Correlation of Distal Mean Arterial Pressure with Aortic Blood Flow during Partial Resuscitative Endovascular Balloon Aortic Occlusion (P-REBOA) in a Swine (*Sus scrofa*) Controlled Hemorrhage Model.

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Dr. Austin Johnson

DEPARTMENT: SGSE

PHONE #: 608-712-7152

INITIAL APPROVAL DATE: 16 February 2017

LAST TRIENNIAL REVISION DATE: N/A

FUNDING SOURCE:

1. RECORD OF ANIMAL USAGE:

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
<i>Sus scrofa</i>	8	8	8

2. PROTOCOL TYPE / CHARACTERISTICS: (Check all applicable terms in **EACH** column)

<input type="checkbox"/> Training: Live Animal	<input type="checkbox"/> Medical Readiness	<input type="checkbox"/> Prolonged Restraint
<input type="checkbox"/> Training: non-Live Animal	<input type="checkbox"/> Health Promotion	<input type="checkbox"/> Multiple Survival Surgery
<input type="checkbox"/> Research: Survival (chronic)	<input type="checkbox"/> Prevention	<input type="checkbox"/> Behavioral Study
<input checked="" type="checkbox"/> Research: non-Survival (acute)	<input type="checkbox"/> Utilization Mgt.	<input type="checkbox"/> Adjuvant Use
<input type="checkbox"/> Other ()	<input type="checkbox"/> Other (Treatment)	<input type="checkbox"/> Biohazard

3. PROTOCOL PAIN CATEGORY (USDA): (Check applicable) ☐ C ☒ D ☐ E

4. PROTOCOL STATUS:

***Request Protocol Closure:**

☐ Inactive, protocol never initiated

☐ Inactive, protocol initiated but has not/will not be completed

☒ Completed, all approved procedures/animal uses have been completed

5. **Previous Amendments:**

List all amendments made to the protocol. IF none occurred, state NONE. Do not use N/A.

For the Entire Study Chronologically

Amendment Number	Date of Approval	Summary of the Change
1	6 March 2017	Procedural/ protocol objective changes
2	20 July 2017	Personnel

6. **FUNDING STATUS:** Funding allocated: \$13,230.00

Funds remaining: \$0.00

7. **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? ☒ Yes ☐ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

<u>NAME</u>	<u>PROTOCOL FUNCTION</u>	<u>IACUC APPROVAL</u>
Capt Harris Kashtan	AI	Yes
Capt Carl Beyer	AI	Yes
Capt Andrew Wishy	AI	Yes

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

<u>NAME</u>	<u>PROTOCOL FUNCTION</u>	<u>DATE OF DELETION</u>
Lt Col Timothy Williams	PI	20 July 2017
Maj Erik DeSoucy	AI	20 July 2017
Capt Meryl Simon Logan	AI	20 July 2017
Capt Emily Tibbits	AI	20 July 2017

8. **PROBLEMS / ADVERSE EVENTS:** Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

No adverse events effected the study. There were no unanticipated events requiring reporting to the IACUC.

9. **REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:**

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

- No

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

- No

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

- No

10. PUBLICATIONS / PRESENTATIONS: (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

- Abstract submitted for presentation to European Congress for Trauma and Emergency Surgery – awaiting outcome

- Manuscript being prepared for Journal of Endovascular Trauma Management – to be submitted

11. PROTOCOL OBJECTIVES: (Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?)

- The study revealed that predicting aortic flow using only distal MAP and proximal MAP during partial REBOA is not possible.

- The relationship is not linear and requires further investigation to advance the understanding of flow and pressure in the case of partial REBOA and extending life in exsanguinating hemorrhage.

- The protocol showed a subgroup of animals who became more hypertensive after transitioning from REBOA to Partial REBOA. These were the animals who

12. PROTOCOL OUTCOME SUMMARY: (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

Protocol Objectives: To analyze the relationship between aortic flow, distal MAP and proximal MAP during partial REBOA to assess if there is a relationship for use in future survival studies.

Materials and Methods: Five anaesthetized Yorkshire swine weighing 59-89kg were prepared in a standard fashion with vascular access and an aortic flow sensor. Using an automated syringe driver to control balloon volume, animals were subjected to a series of phases of zone 1 REBOA and low flow P-REBOA in different states of hemodynamic shock (0, 10, 20, 30 and 40%). Aortic flow, proximal and distal pressures and central venous pressures were recorded. After the 40% phase, animals were euthanized.

Results: During the long occlusive phase, all animals showed an initial rise in pMAP which plateaued before a secondary increase after 5 minutes. Two animals (59kg and 89kg) survived all phases of shock. In shock states of 0-30%, these 2 animals (P1871 and P1889) showed a further rise in pMAP after transitioning from 3 minutes of REBOA to P-REBOA (figure). A drop or no change in pMAP was observed in the 3 early deaths.

Conclusions: The relationship between MAP and aortic flow in the presence of P-REBOA is complex and not linear. Transitioning from REBOA to P-REBOA after a short occlusion can lead to a temporary secondary rise in pMAP. This was associated with longer surviving animals and could be used as a good prognostic indicator during resuscitation. The mechanism behind this finding is unknown and warrants further investigation

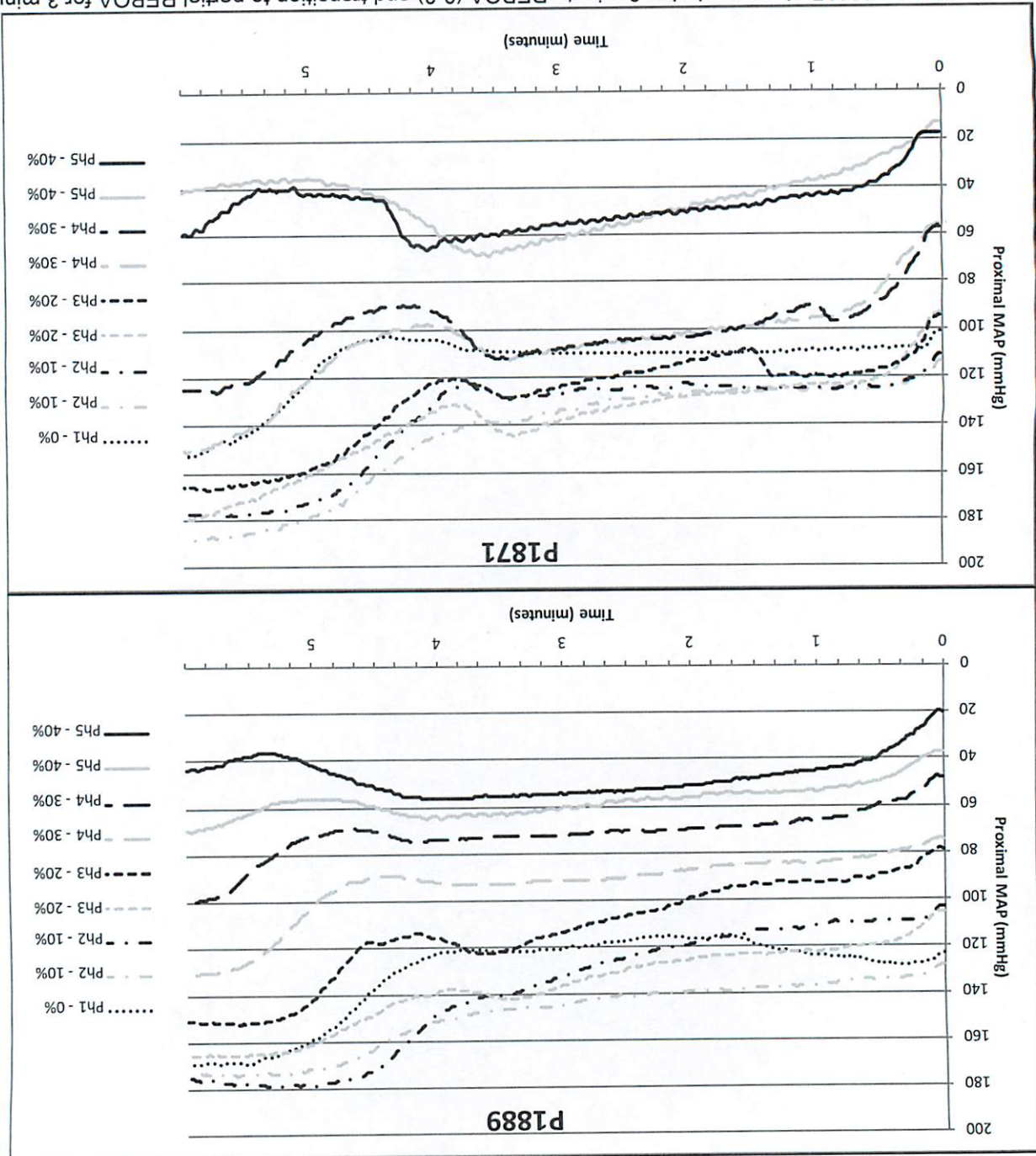
Attachments: Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission (Mandatory)

Dr. Austin Johnson

(Date)

11/22/17

Figure: Proximal MAP changes during 3 minute REBOA (0-3) and transition to partial REBOA for 3 minutes (3-6) in 2 animals who survived whole protocol.



Attachment 1

Defense Technical Information Center (DTIC) Abstract Submission

This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

Objectives:

To analyze the relationship between aortic flow, distal and proximal MAP during partial REBOA.

Methods:

Five anaesthetized Yorkshire swine were prepared in a standard fashion with vascular access and an aortic flow sensor. Using an automated syringe driver to control balloon volume, animals were subjected to a series of phases of zone 1 REBOA and low flow P-REBOA in different states of hemodynamic shock. Aortic flow, proximal and distal pressures were recorded. At the end of the protocol, animals were euthanized

Results:

During the long occlusive phase, all animals showed an initial rise in pMAP which plateaued before a secondary. Two animals survived all phases of shock. In shock states of 0-30%, these 2 animals showed a further rise in pMAP after transitioning from 3 minutes of REBOA to P-REBOA. A drop or no change in pMAP was observed in the 3 early deaths.

Conclusion:

The relationship between MAP and aortic flow in the presence of P-REBOA is complex. Transitioning from REBOA to P-REBOA after a short occlusion can lead to a temporary secondary rise in pMAP. This was associated with longer surviving animals. The mechanism behind this finding is unknown and warrants further investigation.

Grant Number: _____

From: _____

****If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**